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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,342	10/23/2001	Michael Sogard	NIKOP027/PA0427	7706
22852	7590	05/04/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			SHIBUYA, MARK LANCE	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,342	SOGARD, MICHAEL	
	Examiner	Art Unit	
	Mark L. Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/6/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-41, 43, 44 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-41, 43, 44, 47 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/17/05; 2/6/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 33-41, 43, 44, 47-52 are pending. Claim 48 is withdrawn. Claims 33-41, 43, 44, 47, 49-52 are examined.

Amendments

2. The Claims were amended 5/17/2005, but were found non-responsive for being drawn to a different invention (see Office communication, mailed 8/3/2005). The claims, as amended 5/17/2005, were amended again (although never examined) and entered 9/1/2005. In the interest of compact prosecution the claims entered 9/1/2005 are examined herein.

Election/Restrictions

3. Applicant's election with traverse of the species of fluorescent label in the reply filed on 2/06/2006 is acknowledged. The traversal is on the ground(s) that that searching all of the species of label would not impose a serious burden on the examiner. This is not found persuasive in regards to fluorescent versus luminescent labels, because these different labels have materially different design, modes of operation, and function. For example, fluorescence and luminescence are different physical phenomena, and descriptions of labels that utilize fluorescence or luminescence are to be found in different areas in the scientific literature. The species requirement in regard to primary versus secondary label is withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

4. Claim 48 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/06/2006.

Priority

5. This application was filed 10/23/2001.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on May 17, 2005 and February 6, 2006, have been considered by the examiner. The year for foreign patent document DE 36 22 591 C2 was corrected by the examiner, and said document was considered only to the extent of the supplied English abstract.

Withdrawn Rejections

7. The rejection of Claims 33-37 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's amendment.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 33-41, 43, 44, 47, 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a rejection for new matter. This rejection is necessitated by applicant's amendments to the claims, filed 9/1/2005.

The claims are now amended to claim "the movement of the DNA through the solution is in a direction parallel to the temperature gradient." Applicant must point, with particularity, as to where in the specification as filed, support may be found for this new limitation to the claims. The examiner respectfully notes that the limitation does not indicate in which parallel direction the DNA moves through solution. The examiner respectfully notes that the term "parallel" does not seem to appear in the specification, as filed.

Claim Rejections - 35 USC § 102

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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11. Claims 33-35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ke et al., Nucleic Acids Research, 1996, Vol. 24, No. 4, pp. 707-712. This rejection is maintained for the reasons of record as set forth in the previous Office action. The rejection is copied below for the convenience of the reader.

The claims are drawn to an apparatus comprising a container having a solution of DNA therein; and a temperature control system, wherein said temperature control system creates thermal gradients in the solution which result in the redistribution of DNA.

Ke et al., throughout the publication, and especially at the abstract, p. 702, para 3-p. 708, para 4, and Figure 4, teach an apparatus that resembles a conventional vertical gel electrophoresis unit reads on a container with inlet and outlet ports (as in claim 34), optical access to the unit (as in claim 35), and wherein the unit comprises at least some plastic (as in claim 37), wherein the unit generates parallel or perpendicular temperature gradients that are established by aluminum heating plates sandwiching glass plates, between which a solution of DNA is run through an acrylamide gel; and a further comprises a temperature control system that creates thermal gradients in the solution which determines the electrophoretic mobility of DNA, resulting in the redistribution of DNA.

Response to Arguments

Applicant argues that in contrast to the temperature gradient gel electrophoresis apparatus of Ke, the claimed invention does not rely on the use of electrophoresis to drive the movement of the target molecule. Rather, the claimed invention has a temperature gradient is sufficient to drive the movement of the target molecule through the solution.

Applicant's arguments entered 5/17/2005, have been fully considered but they are not persuasive. Absent evidence to the contrary, a DNA molecule in solution in the apparatus of Ke would be moved inherently by the temperature gradient, according to natural phenomena.

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12. Claims 33-41, 43, 44, 47, 49, 51 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Blumenfeld et al., US 6,733,729. This rejection is maintained for the reasons of record as set forth in the previous Office action. Extension of this rejection to new claims is necessitated by the amendments to the claims. The rejection is copied below for the convenience of the reader.

The claims are drawn to an apparatus comprising a container having a solution of DNA therein; and a temperature control system, wherein said temperature control system creates thermal gradients in the solution which result in the redistribution of DNA.

Blumenfeld et al., US 6,733,729, throughout the patent, and at col. 10, line 66-col. 16, line 22, teach an apparatus comprising a container that is a fluidic cell having a base, a glass slide, liquid and a cover, a slide assembly having two slides with acrylamide gel disposed between the slide, or a silicon DNA chip; at col. 5, line 65-col. 8, line 56, teach a wafer that conducts a thermal gradient, and at col. 7, lines 31-40, a gradient apparatus that includes control circuitry and temperature control system. The temperature control system creates thermal gradients in the wafer that, in turn, creates thermal gradients that are transferred to strata placed on the wafer (specification at col. 5, lines 5-12). The strata may comprise nucleic acid, such as DNA, or DNA chip (specification at col. 13, line 64-col. 14, line 15). Blumenfeld teaches that samples can be placed on the strata having a thermal gradient, in order to assess thermal stability at a variety of temperatures, (col. 12, lines 17-27). The thermal gradient changes the stability of DNA hybridization as function of location on the thermal, and results in DNA from certain locations on the gradient washing away, thereby resulting in the redistribution of the DNA into solution (e.g., col. 13, line 64-col. 14, line 15). The reference of Blumenfeld, at col. 11, lines 25-54, teaches embodiments that disclose a microscope slide and coverslip with a small drop (approximately 50 microliters, encompassed by the limitations of claim 36) of water containing DNA (col. 10, line 66-col. 11, line 38); or a DNA chip fluidic containing a glass microscopic slide and liquid film with a volume of approximately 120 microliters, (encompassed by the limitations of claim 36), wherein the base of the fluidic cell is made from lucite, which reads on a container that is plastic, (as in claim 37), and fill holes, for introducing fluid, and which absent evidence to the contrary, may be used for removing fluid, thereby reading on inlet and outlet ports, (as in claim 34). Blumenfeld, at col. 11, line 65-col. 12, line 16, discloses an embodiment comprising an acrylamide gel. Blumenfeld at col. 1, line 66-col. 2, line 17, contemplates detection methods, including microscope systems which, in relation to the aforementioned microscope slide and coverslip, which read on apertures to permit optical access to the container (as in claim 35).

In regard to newly added claims 38-41, 43, 44, 47, 49, 51 and 52, Blumenfeld at, e.g., col. 10, line 14-15, and line 20, teaches a temperature gradient that can be about 10 degrees C./mm and 3.7 degrees C./mm; teach a temperature gradient would inherently cause at a portion of the solution to be warmer than the remainder of the solution and that would inherently move DNA; teaches a DNA nucleic acid

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polynucleotide; Blumenfeld at col. 12, line 64-col. 13, line 9 teaches fluorescent labels that are a primary label or a secondary label..

Response to Arguments

Applicant argues that the temperature gradients described by Blumenfeld are not sufficient strength to result in the thermophoretic force required to move the target molecules through a solution. Moreover, the performance of Blumenfeld's method improves as the gradient is reduced; whereas the performance of the presently claimed invention improves as the gradient increases. Finally the temperature gradients used in the claimed invention are substantially perpendicular to the surface of the substrate whereas the temperature gradient in Blumenfeld is parallel to the surface of a substrate.

Applicant's arguments entered 5/17/2005, have been fully considered but they are not persuasive.

In regards as to where the temperature gradients described by Blumenfeld are not sufficient strength to result in movement of the DNA, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness."). MPEP 2145.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the performance of the presently claimed invention improving as the gradient increases, or that the temperature gradients used in the claimed invention are substantially perpendicular to the surface of the substrate) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In particular, the claims do not recite limitations as to performance or to substrates or surfaces.

13. Claims 33-35, 41, 43, 44, 47, and 49-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakao et al., US 6,589,740. This rejection is maintained for the reasons of record as set forth in the previous Office action. Extension of this rejection to new claims is necessitated by the amendments to the claims. The rejection is copied below for the convenience of the reader.

The claims are drawn to an apparatus comprising a container having a solution of DNA therein; and a temperature control system, wherein said temperature control system creates thermal gradients in the solution which result in the redistribution of DNA.

Nakao et al., throughout the patent, and at col. 4, line 59-col. 5, line 6, teach an apparatus (that reads on the container of the claimed invention) for imposing a thermal gradient on a slab gel containing oligonucleotides, wherein the apparatus contains inlet and outlet ports for hot and cold water flow; at col. 12, lines 18-36, wherein the temperature gradient is a denaturing gradient; at col. 12, line 62-col. 13, line 22, wherein the gradient is generated by temperature control equipment; at col. 3, lines 19-33, and at col. 3, lines 59-10, teach the hybridizing molecule as DNA; at col. 1, line 65-col. 2, line 27 and Fig. 5, teach that denaturing gel electrophoresis (including where the denaturant is a thermal gradient) as resulting in changes in the electrophoretic migration of nucleic acids (which reads on redistribution in solution); and at Fig. 4, for example, show DNA gels, demonstrating optical access to the container, as in claim 35.

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In regard to newly added claims 41, 43, 44, 47, 49, 50, 51 and 52, Nakao at col. 12, teaches a temperature gradient that would inherently cause at a portion of the solution to be warmer than the remainder of the solution and, absent evidence to the contrary, would inherently drive DNA; teaches a DNA nucleic acid polynucleotide; at col. 4-5, teaches inlet and outlet ports; Nakao at col. 1, lines 25-30, teach a fluorescently labeled DNA which may be considered a primary or secondary label, depending on whether the DNA that moves is the probe or DNA that becomes detached from the array.

Response to Arguments

Applicant argues that Nakao does not teach or suggest the use of thermophoresis to drive the movement of a target molecule through a solution, so that not every element of the claims is shown.

Applicant's arguments entered 5/17/2005, have been fully considered but they are not persuasive. Any DNA molecule in solution in the apparatus of Nakao would be moved inherently by the temperature gradient, according to natural phenomena.

Conclusion

14. Claims 33-41, 43, 44, 47, 49-52 stand finally rejected.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Mark L. Shibuya
Examiner
Art Unit 1639